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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,507	10/14/2003	Bernard Andreas	021629-001900US	3531

20350 7590 04/14/2008

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EXAMINER	
OU, JING RUI	

ART UNIT	PAPER NUMBER
3773	

MAIL DATE	DELIVERY MODE
04/14/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/686,507	ANDREAS ET AL.	
	Examiner	Art Unit	
	JING OU	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *4 and 14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 5-13, and 15-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *03/12/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This action is responsive to the amendment filed on February 28, 2008. Claims 1-20 are pending. Claims 1 and 11 are independent. Claims 4 and 14 are withdrawn from consideration.

Information Disclosure Statement

2. The information disclosure statement filed 03/12/2008 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 103

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-2, 5-12, 15-18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chermoni (US Pub. No.: 2002/0156496 A1) in view of Keith et al (US Pat. No.: 6,070,589).

In regard to claim 1-2, 5-12, 15-18 and 20, Chermoni discloses:

A) a stent delivery device for delivering a plurality of stent segments to a treatment site, the device comprising: a catheter shaft (124, Fig. 1) having a proximal end and a distal end; an expandable member (balloon, 104, Fig. 7) coupled with the catheter shaft near the distal end; a shuttle (carriage, 605, Fig. 7) disposed coaxially over at least part of the catheter shaft and the expandable member, at least part of the shuttle being radially expandable (Para. [0042]); and a plurality of stent segments (206a, 206b, 206c, Fig. 7) disposed along the shuttle;

B) the shuttle is slidably disposed over at least part of the catheter shaft and the expandable member (Para. [0041]);

C) the stent segments are fixed to the shuttle until they are expanded into a deployed position (Paras.[0041]-[0042]);

D) the stent segments are slidable (Para.[0041]), the device further comprising a stent-pushing member (106, Fig. 7), proximal to the plurality of stent segments.

E) the shuttle further comprises an abutment (barrier, next to 610a, Fig. 7) at or near a distal end of the shuttle for preventing the plurality of stent segments from being advanced beyond the distal end of the shuttle;

Chermoni does not appear to discloses:

A) an axially movable sheath disposed over at least part of the catheter shaft and the expandable member and moving the sheath axially toward the proximal end of the catheter shaft allows at least part of the expandable member to expand against the shuttle to cause the shuttle to radially expand, thus causing at least one of the plurality of stent segments to expand; the sheath having a reinforced distal portion.

B) sheath is disposed over the shuttle;

The recitations, “adapted to resist radial expansion of the expandable member " and " while a remaining portion of the expandable member is constrained by the sheath" in Claim 1, “the sheath is adapted to expose a first portion of the expandable member to deploy a first selected number of stent segments” in Claim 6, and “the sheath is adapted to further expose at least a second portion of the expandable member to deploy a second selected number of stent segments” in Claim 7 are intended use recitations. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim limitation.

However, Keith et al explicitly discloses:

A) an axially movable sheath (delivery sheath, 60R, Fig. 11) disposed over at least part of the catheter shaft (lead balloon catheter, 68R, Fig. 4) and the expandable member (balloon, 70R, Fig. 4) and moving the sheath axially toward the proximal end of the catheter shaft allows at least part of the expandable member to expand, thus causing a stent (aortic stent, 64R, Fig. 4) to expand (Col. 12, lines 48-51, the expansion of the balloon causes the stent to expansion); the sheath having a reinforced distal portion (Col. 6, lines 65-67 and Col. 7, lines 1-2, Keith et al discloses a sheath having a reinforced layer throughout the sheath).

B) the sheath is disposed over the distal portion of the outer shaft of catheter that carries the stent (Figs. 4 and 11);

In addition, the sheath of Keith et al meets the functional limitation, “a remaining portion of the expandable member is constrained by the sheath." (Col. 7, lines 6-11 and Figs. 10-13)

Chermoni and Keith et al are analogous art because they are from the same field of endeavor.

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Chermoni and Keith et al before him or her, to modify the stent delivery device of Chermoni to include an axially movable sheath and replace the stent push member of Chermoni by a pusher tube (ledge, 72, Fig. 4) as taught by Keith et al.

The suggestion/motivation for modifying a sheath to include a reinforced layer would have been to add column strength or kink resistance (Col. 6, lines 65-67 and Col. 7, lines 1-2). Applicant should note that it is well-known in the art that an axial movable sheath is used to keep a stent to remain unexpanded and prevent a stent from deploying at an undesired location. It is also well-known that a pusher tube/ledge is used to push the stent out a sheath.

Therefore, it would have been obvious to combine Keith et al with Chermoni to obtain the invention as specified in the instant claims.

6. Claims 3 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chermoni (US Pub. No.: 2002/0156496 A1) in view of Keith et al (US Pat. No.: 6,070,589) as applied to claims 1 and 11 above, and further in view of Shaknovich (US Pat. No.: 5,807,398).

In regard to claims 3 and 13, Chermoni and Keith et al disclose all the limitations of the claim as taught above but fail to disclose that the shuttle is fixedly disposed over at least part of the catheter shaft and the expandable member.

However, Shaknovich explicitly discloses a shuttle (1, Fig. 1) that is fixedly disposed over at least part of the catheter shaft (7, Fig. 1) and the expandable member (8, Figs 1 and 4 and Col. 4, lines 22-31).

Chermoni, Keith et al, and Shaknovich are analogous art because they are from the same field of endeavor.

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teaching of Chermoni, Keith et al, and Shaknovich before him or her

to modify the stent delivery device of Chermoni and Keith et al to include a shuttle that is fixedly disposed over at least part of the catheter shaft and the expandable member of Shaknovich.

The motivation/suggestion for doing so would have been to be advanced into a patient as a shuttle-balloon catheter assembly (Shaknovich, Col. 11, lines 1-16).

Therefore, it would have been obvious to combine Shaknovich with Chermoni and Keith et al to obtain the invention as specified in the instant claims.

7. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chermoni (US Pub. No.: 2002/0156496 A1) in view of Keith et al (US Pat. No.: 6,070,589) as taught in Claim 11, and further in view of Martinez et al (US Pat. No.: 5,593,412).

In regard to Claim 19, Chermoni in view of Keith et al discloses all the limitations the claim as taught above but fails to disclose at least one valve member coupled with the sheath for selectively retaining at least one stent segment within the sheath.

However, Martinez et al explicitly discloses valve members coupled with the sheath (51-55, Fig. 2B).

Chermoni, Keith et al, and Martinez et al are analogous art because they are from the same field of endeavor.

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Chermoni in view of Keith et al and Martinez et al before him or her, to modify the stent delivery device of Chermoni in view of Keith et al to include the valve members coupled with the sheath as taught by Martinez et al.

Applicant should note that it is well-known in the art that the valve members coupled with the sheath keeps the stent from premature deployment.

Therefore, it would have been obvious to combine Martinez et al with Chermoni and Keith et al to obtain the invention as specified in the instant claim.

8. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chermoni (US Pub. No.: 2002/0156496 A1) in view of Keith et al (US Pat. No.: 6,070,589) as taught in Claim 11, and further in view of Palermo (US Pat. No.: 5,312,415)

In regard to Claim 19, Chermoni in view of Keith et al discloses all the limitations the claim as taught above but fails to disclose at least one valve member coupled with the sheath for selectively retaining at least one stent segment within the sheath.

However, Palermo explicitly discloses a sheath with a constricted distal end (104, Fig. 1).

Chermoni, Keith et al, and Palermo are analogous art because they are from the same field of endeavor.

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Chermoni in view of Keith et al and Palermo before him or her, to modify the stent delivery device of Chermoni in view of Keith et al to include a sheath with a constricted distal end as taught by Palermo.

The suggestion/motivation for doing so would have been to control the discharge of the coil through the catheter sheath distal tip (Palermo, Col. 3, lines 67-68 and Col. 4, lines 1-3)

Therefore, it would have been obvious to combine Palermo with Chermoni and Keith et al to obtain the invention as specified in the instant claim.

9. Claims 1-3, 5-9, 11-13, 15-17, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shaknovich (US Pat. No.: 5,807,398) in view of Keith et al (US Pat. No.: 6,070,589).

In regard to Claims 1-3, 5-9, 11-13, 16-17, and 20, Shaknovich discloses a stent catheter system, comprising: a catheter shaft (7, Fig. 4), an expandable member (balloon, 8, Fig. 4), an axially movable sheath (13, Fig. 6), a shuttle (1, Fig. 1), a plurality of stent segments (3a, Fig. 9), the shuttle is slidably disposed over at least part of the catheter shaft and the expandable member when the expandable member is deflated, the shuttle is fixedly disposed over at least part of the catheter shaft and the expandable member when the expandable member is inflated, the stent segments are fixed to the shuttle until they are expanded into a deployed position, and the stent segments are slidably disposed along the shuttle when the expandable member is deflated.

Shaknovich fails to explicitly disclose that the sheath has a reinforced distal portion and a stent-pushing member.

However, Keith et al teaches a stent delivery system, comprising: a sheath (delivery sheath, 60R, Fig. 11) having a reinforced distal portion (Col. 6, lines 65-67 and Col. 7, lines 1-2, Keith et al discloses a sheath having a reinforced layer throughout the sheath) and a stent-pushing member (ledge, 72R, Fig. 4).

Shaknovich and Keith et al are analogous art because they are from the same field of endeavor.

Therefore, it would have been obvious to combine Keith et al with Shaknovich to obtain the invention as specified in the instant claims. The suggestion/motivation for modifying the sheath of Shaknovich to include a reinforced layer as taught by Keith et al would have been to add column strength or kink resistance (Keith et al, Col. 6, lines 65-67 and Col. 7, lines 1-2). Applicant should have noted that it is old and well-known that a pusher tube/ledge located on the proximal end of a stent is used to push the stent out a sheath.

10. Claims 10 and 18 rejected under 35 U.S.C. 103(a) as being unpatentable over Shaknovich (US Pat. No.: 5,807,398) in view of Keith et al (US Pat. No.: 6,070,589) as applied to claims 1 and 11 above, and further in view of Chermoni (US Pub. No.: 2002/0156496).

In regard to Claims 10 and 18, Shaknovich in view of Keith et al discloses all the limitations of the claims but fails to teach an abutment at or near a distal end of the shuttle.

However, Chermoni explicitly teaches an abutment (the protrusion/barrier at the most distal end of the carriage/shuttle 605 as shown in Fig. 6) at or near a distal end of the shuttle.

Therefore, it would have been obvious to combine Chermoni with Shaknovich and Keith et al to obtain the invention as specified in the instant claims. Applicant should have noted that it is old and well-known that such abutment would have been to provide a barrier to prevent the stent segments from being advanced beyond the distal end of the shuttle.

11. Claims 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shaknovich (US Pat. No.: 5,807,398) in view of Keith et al (US Pat. No.: 6,070,589) as applied to claim 11 above, and further in view of Palermo (US Pat. No.: 5,312,415)

In regard to Claim 19, Shaknovich in view of Keith et al discloses all the limitations the claim as taught above but fails to disclose at least one valve member coupled with the sheath for selectively retaining at least one stent segment within the sheath.

However, Palermo explicitly discloses a sheath with a constricted distal end (104, Fig. 1).

Shaknovich, Keith et al, and Palermo are analogous art because they are from the same field of endeavor.

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Shaknovich in view of Keith et al and Palermo before him or her, to modify the stent delivery device of Shaknovich in view of Keith et al to include a sheath with a constricted distal end as taught by Palermo.

The suggestion/motivation for doing so would have been to control the discharge of the coil/ stent /vascular device through the catheter sheath distal tip (Palermo, Col. 3, lines 67-68 and Col. 4, lines 1-3)

Therefore, it would have been obvious to combine Palermo with Shaknovich and Keith et al to obtain the invention as specified in the instant claim.

Response to Arguments

12. Applicant's arguments with respect to claims 1-20 have been considered but are moot in view of the new ground(s) of rejection.

As noted above, all of the claimed structure is found in references and the examiner contends that the prior art is capable of performing the claim functions.

In response to applicant's argument stated on pages 8 and 9 of the remarks, "if a portion of the balloon were constrained by the sheath while the stent is position on it, only a portion of the stent would be expanded, thereby preventing the stent from performing its function of scaffolding the diseased vessel, and potentially preventing the stent from being removed from the vessel due to partial expansion of its distal end," the remarks is incorrect. While it may be true that only a portion of the stent would be expanded if a portion of the balloon were constrained by the sheath while the stent is position on it, it is not necessarily preventing the stent from performing its function of scaffolding the diseased vessel, and potentially preventing the stent from being removed from the vessel due to partial expansion of its distal end. At the moment when the sheath is withdrawn proximally, the distal portion of the stent would expand. However, at that moment, the proximal portion of the stent along with the portion of the balloon covered by the sheath is still compressed by the sheath. As shown in Keith et al, the process of retracting the sheath along with the expansion of the stent requires a plurality of steps as shown in Figures 19-27.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JING OU whose telephone number is (571)270-5036. The examiner can normally be reached on M-F 7:30am - 5:00pm, Alternative Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Uyen (Jackie) T Ho can be reached on (571)272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JRO

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